

Application No. 10/625,633
Amendment Dated November 30, 2010
Reply to Office Action dated August 31, 2010

REMARKS

The Office Action of August 31, 2010 has been reviewed and carefully considered by the applicants.

Claim Status

Claims 1, 11, 28, 72, and 73 are currently amended. Claims 12-14, 16, 17, 68, 69, 71, and 74-84 are cancelled. New claims 85 and 86 are added. No new matter has been added with the amendments to the claims. The application is currently presented with claims 1-3, 5-11, 28, 72, 73, 85, and 86.

Interview Summary

The applicants thank the Examiner for his time in conducting a telephonic interview with the applicants' undersigned representative on November 18, 2010. In view of the discussion of that interview, the claims have been amended to focus the claims on subject matter that the applicants believe to be allowable.

Claim Rejections under 35 USC §102

The Examiner has rejected the previously presented claims under 35 USC §102(e) as being anticipated by Zhou et al US Published Patent Application No. 2003/0149526 (hereinafter "Zhou"). The current amendments to the independent claims have been made to highlight features that are distinguished in the disclosed systems and methods from those disclosed by Zhou. Each independent claim will be addressed individually herein.

Claim 1

Currently amended claim 1 includes:

a first logic rule set for diagnosing a physiological condition of a patient, the first logic rule set including a plurality of logic rules for interpreting the plurality of physiologic variables of the real-time physiologic data stream;

a second logic rule set for diagnosing a physiological condition of the patient, the second logic rule set including a plurality of logic rules for interpreting the physiological variables of the real-time physiological data stream; and

a controller that receives said real-time physiologic data stream, said controller including a logic that simultaneously cross references said plurality of physiologic variables of the real-time physiologic data stream with the first logic rule set and second logic rule set, and generates at least a first diagnostic interpretation of said plurality of physiologic variables utilizing said first logic rule set and a second diagnostic interpretation of said plurality of physiologic variables utilizing said second logic rule set;

wherein the first diagnostic interpretation and the second diagnostic interpretations are different diagnostic interpretations of the same physiological condition, using the same real-time physiologic data stream.

The newly highlighted features of claim 1 distinguish the claimed monitoring assembly from that disclosed by Zhou particularly in that the first logic rule set and the second logic rule set are both *for diagnosing a physiological condition of a patient*. Through the use of antecedent basis, it is identified that the physiological condition of the patient diagnosed by both of the first and second logic rule sets are the same physiological condition. As will be argued in further detail herein, Zhou fails to disclose a first and a second logic rule set that produces a first and a second diagnostic interpretation. However, even if this disclosure is accepted for the sake of argument, Zhou fails to disclose that the first and second logic rule sets are both logic rule sets for diagnosing the same physiological condition of the patient.

Additionally, the monitoring assembly of claim 1 simultaneously cross references said plurality of physiologic variables of the real-time physiologic data stream with the first logic rule set and second logic rule set. Zhou fails to disclose simultaneous application of a first logic rule set and a second logic rule set to a real-time physiologic data stream. This is an important feature as it distinguishes the serial application of a plurality of interpretation rules to physiological data as disclosed in Zhou.

In order to present the clinician with a diagnosis aid, as claimed, the first logic rule set and the second logic rule set must be applied *simultaneously* to the real-time physiologic data stream such that the first diagnostic interpretation and the second diagnostic interpretation result

form the same physiologic variables obtained at the same time, rather than comparing diagnostic interpretations resulting from physiological data that is temporally disparate.

Finally, the monitoring assembly of claim 1 further identifies that the first diagnostic interpretation and the second diagnostic interpretation are different diagnostic interpretations of the same physiological condition using the real-time physiologic data stream. This feature also highlights the distinction over Zhou in that Zhou fails to disclose a first logic rule set and a second logic rule set that are directed to the same physiological condition and produce differing diagnostic interpretations when presented with the same real-time physiologic data stream.

As Zhou fails to disclose each of the above-highlighted features found in the monitoring assembly of claim 1, Zhou fails to anticipate claim 1. Claim 1 is therefore novel over the disclosure of Zhou.

Claims 2, 3, and 5-10 all depend from independent claim 1, which is herein believed to be allowable. Therefore, claims 2, 3, and 5-10 are also believed to be allowable for the reasons stated above with respect to claim 1, as well as for the patentable subject matter recited in each of these claims. The applicants reserve the right to individually address the patentable subject matter of these claims during further prosecution, if required.

Claim 11

Claim 11 is directed to a method for providing diagnostic aid to a clinician. The method of claim 11 includes:

storing a plurality of sets of rule-based algorithms, including a first and a second set of rule-based algorithms, on a data storage device, the first and second sets of rule-based algorithms generating different diagnostic interpretations of the same physiological data representative of the same physiological system;

acquiring a physiological data stream from at least one sensor connected to the patient;

identifying with a logic of a controller, physiological data present in the physiological data stream;

selecting, with the logic of the controller, the first and second sets of rule-based algorithms that generate different diagnostic interpretations of the identified physiological data in the physiological data stream;

The method for providing diagnostic aid to a clinician in claim 11 is novel over the disclosure of Zhou because Zhou fails to disclose the additional sets of identifying physiological data present in the physiological data stream and selecting the first and second sets of rule-based algorithms that generate different diagnostic interpretations of the identified physiological data in the physiological data stream. Therefore, the method of claim 11 is distinguished from the disclosure in Zhou as Zhou fails to include the additional layer of analysis wherein the physiological data stream is first analyzed in order to identify what physiological data is present in the physiological data stream. The method of claim 11 then continues by using the identified physiological data in order to select the first and the second sets of rule-based algorithms from the plurality of sets of rule-based algorithms. As Zhou fails to disclose the claimed relationship between the first and second sets of rule-based algorithms, namely, that both the first and second sets of rule-based algorithms generate different diagnostic interpretations from the same physiological data, the method of claim 11 is novel over the disclosure of Zhou.

Claim 72

Claim 72 is directed to a method for diagnosing the medical condition of a patient. The method of claim 72 includes:

acquiring at least one real-time physiological data stream;

identifying, with a logic operating on a controller, physiological data present in the at least one real-time physiological data stream;

selecting, with the logic, a first rule set comprising rule-based algorithms directed to produce at least one first diagnostic interpretation of the physiological data;

selecting, with the logic, a second rule set comprising rule-based algorithms directed to produce at least one second diagnostic interpretation of the physiological data, wherein the first rule set

and the second rule sets produce different diagnostic interpretations of the same identified physiological data;

applying, with the logic, the first rule set to the acquired at least one real-time physiological data stream to produce at least one first diagnostic interpretation;

applying, with the logic, the second rule set to the acquired at least one real-time physiological data stream to produce at least one second diagnostic interpretation; and

displaying the first and second diagnostic interpretations.

The method of claim 72 is novel over the disclosure of Zhou for reasons similar to those highlighted above with respect to claim 11, but with reference to the specific language of claim 72. More specifically, the method of claim 72 identifies physiological data present in the at least one real-time physiological data stream. The method then goes on to use the identified physiological data in order to select a first rule set that includes rule-based algorithms that produce at least one first diagnostic interpretation of the physiological data and select a second rule set that includes rule-based algorithms directed to produce at least one second diagnostic interpretation of the physiological data. Zhou fails to disclose this combination of steps wherein first the physiological data present in the real-time physiological data stream is identified and then the identified physiological data is used to select the rule-based algorithms of the first rule set and the second rule set.

Additionally, the method of claim 72 goes on to identify that the first rule set and the second rule sets produce different diagnostic interpretations of the same identified physiological data. This further defines and relates the first rule set and the second rule set to one another in that the first and second rule sets produce different diagnostic interpretations of the same identified physiological data. This relation between the first and second rule sets is not disclosed by Zhou wherein Zhou fails to disclose any specified relationship between first and second rule sets.

Therefore, the method of claim 72 is novel over the disclosure of Zhou.

General Comments Regarding Zhou

The Examiner has relied upon the disclosure of Zhou found at paragraph [0022 – 0044] for disclosing the physiological monitoring aspects of the claimed invention. The Examiner relies upon the disclosure found at paragraphs [0081 – 0093] for the logical rule sets as claimed and implemented in the currently presented claims.

The currently presented claims are set forth as a diagnostic aid to a clinician's review of acquired physiological data. This is achieved by using at least a first and a second logic rule set that each includes a plurality of logic rules for interpreting the physiological variable of the acquired data stream. The controller applies both of these logic rule sets to respectively produce a first diagnostic interpretation and a second diagnostic interpretation.

The Examiner has relied upon the disclosure of Zhou, and particularly the disclosure found at paragraph [0082]. In that paragraph, Zhou discloses that "alert threshold evaluation preferably occurs at two levels. A basic threshold evaluation occurs at the device 100, specifically in the microprocessor of the bed unit 204 or the processing unit 260 of the microchip 210 to determine if the device 100 should generate an alert and transmit the data to the ASP 200 as previously described. The second level of alert evaluation is a more sophisticated evaluation that occurs at the ASP 200 using logical rules that will be described in greater detail below." This disclosure of Zhou and the rest of Zhou fails to anticipate the claimed systems and methods for a variety of reasons as highlighted above.

The "basic threshold evaluation" of Zhou serves as a gateway or precursor to determine if the recorded data warrants further processing that is achieved "by using logical rules." Therefore, Zhou does not apply both the first logic rule set and the second logic rule set to produce two different diagnostic interpretations, but rather uses the "basic threshold evaluation to determine what data requires further automated processing." Once again, the claimed systems and methods are for the purpose of facilitating a diagnostic interpretation by a clinician representing an automated differential diagnosis. This is not anticipated by the automated data processing alerts disclosed by Zhou.

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Next, the basic threshold evaluation is not presented to the clinician and therefore cannot be used by the clinician in a comparative process with the diagnostic interpretation produced by the application of the "logical rules" of the second level of alert evaluation.

Finally, Zhou discloses a plurality of individual thresholds and Boolean statements that result in warnings or other alerts to be automatically be sent to a variety of alert devices. Zhou further discloses at [0096] that the clinician can interact through the DP 300 in order to initiate additional alerts. This further highlights the fact that the end goal of the application of the basic threshold evaluation and the second level of alert evaluation of Zhou is to produce automated alarms that are sent to remotely located individuals. Zhou does not disclose or otherwise anticipate the claimed automated differential diagnosis that is produced by the application of a first logic rule set and a second logic rule set that are designed to be applied to the same physiological variables and yet produce different diagnostic interpretations. As this feature has not been shown in Zhou, the current application is novel.

Conclusion

By the present amendments and arguments, the currently presented claims are believed to be novel over the references cited by the Examiner. The applicant therefore believes that the currently presented claims are in condition for allowance. Such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP



Benjamin R. Imhoff
Reg. No. 60,036

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202
Telephone: (414) 271-7590
Facsimile: (414) 271-5770